UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

ARIAD PHARMACEUTICALS, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, and THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE **Plaintiffs,** **v.** **ELI LILLY AND CO.,** **Defendant.**	**Civil Action No. 02 CV 11280 RWZ** **U.S. District Judge Rya W. Zobel**

BENCH MEMORANDUM REGARDING RELEVANCE OF POST-FILING ART IN ASSESSING ENABLEMENT AND WRITTEN DESCRIPTION

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During his testimony today, Lilly's expert witness, Dr. Latchman, testified to literature and knowledge in the art of the '516 patent after the filing date, which is relevant to the issues of both enablement and written description. Mr. Drutchas, however, erroneously suggested that this type of evidence was impermissible in the context of written description.

Thus, Plaintiffs provide the Court with this memorandum to clarify the legal standards governing the relevancy of post-filing art, such as research articles, to prove enablement *and* written description. It undisputed by either side that post-filing success is relevant to enablement. *See, e.g., Plant Genetic Systems, N.V. v. DeKalb Genetics Corp*., 315 F.3d 1335, 65 U.S.P.Q.2d 1452, (Fed. Cir. 2003)(stating the "[d]istrict court properly used post-filing work relevant to later-existing state of art to test whether patent claims were enabled"). A determination of enablement requires assessing the capability of "one of skill in the art to make and use the full scope of the claimed invention." *CFMT, Inc. v. Yieldup Intern. Corp*., 349 F.3d 1333, 1337 (Fed. Cir. 2003). Similarly, "the written description requirement must be applied in the context of the particular invention and the state of the knowledge." *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005).

Courts often examine the literature in the art, as well as the post-filing art, in order to determine the state of knowledge in the relevant art. Just as the inquiry into the state of the art is common to both the enablement and written description standards, the evidence adduced must be common to both as well. *See Amgen Inc. v. Hoechst Marion Roussel*, Inc. 314 F.3d 1313, 1336 (Fed. Cir 2003) (examining numerous post-filing publications to establish what one of skill in the art would have known); *Schering Corp.*

v. Amgen Inc. 222 F.3d 1347,1353 (Cir. Fed. 2000) (assessing the written description and after arising art to determine how "those skilled in the art used the term 'leukocyte interferon'").

Further, while Plaintiffs acknowledge that written description and enablement are distinct requirements under 35 U.S.C. §112, Lilly's insistence on evidentiary limitations that apply to written description and not to enablement is baseless and ignores the common inquiries between them. *Lizardtech, Inc. v. Earth Res. Mapping, Inc*., 424 F.3d 1336, 1345 (Fed. Cir. 2005) (stating the enablement and written description requirements "usually rise and fall together [and t]hat is, a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa").

In re Gabapentin Litigation, 395 F.Supp.2d 175 (D. N. J. 2005) is illustrative of the acceptability of post-filing evidence in making the determination as to whether one of ordinary skill in the art would have understood that the applicants were in possession of the full scope of their invention at the time of filing. *Id.* at 182-83 (considering evidence of scientists' interpretation of gabapentin related literature in the after-art to support that "it is the hydrochloric acid that the inventors discovered was detrimental to gabapentin" thus creating a fact issue and precluding summary judgment that the inventors lacked a sufficient written description).

Particularly in the area of biotechnology, as here, after-art evidence may be a helpful gauge in determining whether one of skill in the art would have considered the disclosure of a patent to be adequate proof of possession of the invention at the time of filing. "Precedent illustrates that the determination of what is needed to support generic

claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter." *Capon*, 418 F.3d at 1359 (Fed. Cir. 2005) (citing *In re Wallach*, 378 F.3d 1330, 1333-34 (Fed.Cir.2004)) (an amino acid sequence supports "the entire genus of DNA sequences" that can encode the amino acid sequence because "the state of the art has developed" such that it is a routine matter to convert one to the other).

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Respectfully Submitted

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on April 6, 2006.

/s/ Vladimir V. Drozdoff